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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/620,000 | 07/14/2003 | Helene Depui | 1103326-0250 CONT. | 7466 |

7470 7590 09/21/2005

WHITE & CASE LLP
PATENT DEPARTMENT
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

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| EXAMINER |
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CHANNAVAJJALA, LAKSHMI SARADA

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| ART UNIT | PAPER NUMBER |
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1615

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/620,000

Applicant(s)

DEPUI ET AL.

Examiner

Lakshmi S. Channavajjala

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-14,23-28,32-34 and 37-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-14,23-28,32-34 and 37-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>5-19-04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of terminal disclaimer and response dated 1-20-05 is acknowledged.

Claims 1, 4-14, 23-28, 32-34 and 37-45 are pending in the instant application.

Response to Arguments

Examiner acknowledges the terminal disclaimer filed in response to the previous rejection. The double patenting rejection applied in the previous action has been withdrawn. However, the following new rejection is applied to the instant claims:

Double Patenting

Claims 1, 4-14, 23-28, 32-34 and 37-45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of U.S. Patent No. 6,365,184 respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because the above patent claims an oral composition, preferably tablet, comprising a proton pump inhibitor and a non-steroidal anti-inflammatory compound, optionally, pharmaceutically acceptable excipients, where the proton pump inhibitor is covered by an enteric coated layer and which is separated from the proton pump inhibitor by an additional layer. Further, the process of preparing the composition is similar in both the instant and the patented claims. Thus, the patented claims anticipate in the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-14, 23-28, 32-34 and 37-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over a US 4,786,505 to Lovgren et al (Lovgren) in view of EP 0426479 (EP).

Lovgren teaches a pharmaceutical preparation comprising proton pump inhibitor, omeprazole, optionally with an alkaline material as a core material and one or more sub coating layers comprising inert compounds and an enteric coating. Lovgren teaches the process of preparing the compositions. Lovgren teaches that the stability of omeprazole is maintained by protecting the compound from contact with gastric juices by adding an enteric coat over the compound, until it reaches small intestine without degradation (col. 1, lines 49-65). In order to increase the stability and rapid dissolution of omeprazole, Lovgren suggests preparing cores containing omeprazole mixed with an alkaline compound, which is further coated two or more layer, one of which is rapidly disintegrating in water and which separates the core from the enteric coating (col. 3, lines 14-33 and col. 4, lines 4-27). Lovgren also teaches the process of preparing and the use of the tablets prepared for treating the gastric acid secretion that reads on the instant process and method claims. Lovgren does not teach a combination of proton pump inhibitor and a non-steroidal anti-inflammatory agent.

EP teaches a pharmaceutical composition for the treating the symptoms of overindulgence comprising an analgesic effective amount of acetaminophen or a NSAID

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and a gastric acid inhibiting effective amount of a proton pump inhibitor. EP teaches that overindulgence is usually caused by excessive or inappropriate food intake and/or alcoholic beverages and results in acid indigestion or sour stomach. EP further teaches no single agent can effectively provide treatment of multiple symptoms of overindulgence. EP also teaches that NSAIDs, used for treating pain and inflammation, themselves cause stomach upset and therefore a combination of drugs is effective in treating the acid indigestion. EP also teaches various doses of NSAID and proton pump inhibitors, depending the specific drug used (col. 6).


It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use a non-steroidal anti-inflammatory compound together with a proton pump inhibitor, such as omeprazole because EP teaches that a combination of proton pump inhibitor and NSAID is better in treating acid indigestion than either alone and that NSAIDs themselves cause acid indigestion. Thus, a skilled artisan would have expected to effective treatment of gastric acid secretion with a combination of proton pump inhibitor and a NSAID. Further, optimizing the amounts of each of the compounds, depending on the specific drug being employed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Lakshmi S Channavajjala
Examiner
Art Unit 1615
September 16, 2005